05-02-05

DPW

Patent Application
Attorney Docket No.PC11724G
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By Deanna L Shields
(Signature of person mailing)
Deanna L. Shields
(Typed or printed name of person)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Zheng J. Li, et al. :

APPLICATION NO.: 10/652,933 : Examiner: Unknown

FILING DATE: August 28, 2003 : Group Art Unit: 1623

TITLE: CRYSTAL FORMS OF AZITHROMYCIN :

Hon. Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450
ATTN: Technology Center Special Program Examiner

Sir:

PETITION TO MAKE SPECIAL UNDER 37 C.F.R. § 1.102

Applicants hereby request that the present application be made special for accelerated examination under 37 C.F.R. § 1.102 and M.P.E.P. § 708.02 (VIII).

REQUIREMENT OF M.P.E.P. § 708.02 (VIII)(A) - FEE

The commissioner is authorized to charge the fee set forth in 37 C.F.R. 1.17(h) in the amount of $130.00 to our Deposit Account No. 16-1445 for consideration of the present petition. Therefore, Applicants have satisfied the requirement of M.P.E.P. § 708.02 (VIII)(A).

REQUIREMENT OF M.P.E.P. § 708.02 (VIII)(B) – SINGLE INVENTION

Applicants have concurrently filed a Second Preliminary Amendment canceling all pending claims without prejudice and added new claims 136-145 which are directed to pharmaceutical composition comprising substantially pure Form F and a pharmaceutically

acceptable carrier or diluents. Applicants respectfully submit that new claims 126-145 are directed to a single invention (a copy of new claims 126-145, together with a copy of the PCT claims are enclosed herein). However, if the Patent Office determines that all the claims presented are not obviously directed to a single invention, Applicants will make an election without traverse. Applicants respectfully submit that the requirements of M.P.E.P. § 708.02 (VIII)(B) have been met.

REQUIREMENT OF M.P.E.P. § 708.02 (VIII)(C) – PRE-EXAMINATION SEARCH

M.P.E.P. § 708.02 (VIII)(C) requires the submission of a statement on pre-examination search. Applicants note that such requirement can be met by a search made by a foreign patent office if the claims in the corresponding foreign application are of the same or similar scope to the claims in the U.S. application for which special status is requested.

Applicants would like to point out that a search was made by the International Searching Authority/European Patent Office and the claims in the PCT application are of similar scope to the claims in the present U.S. application. For your convenience, a copy of the pending PCT claims is enclosed as well as copies of the PCT search report and the written opinion. Therefore, Applicants have satisfied the requirement of M.P.E.P. § 708.02 (VIII)(C).

REQUIREMENT OF M.P.E.P. § 708.02 (VIII)(D) – COPIES OF THE REFERENCES

The PCT search report cited the following nine references:

Ref. 1 EP 0298650A (Pfizer), January 11, 1989;

Ref. 2 EP 1103558A (Astur Pharma S A), May 30, 2001;

Ref. 3 WO 0100640A (Ludescher Jonannes), January 4, 2001;

Ref. 4 CA 2245398A (Motamedi M), February 21, 2000;

Ref. 5 WO 00 32203A Singer Claude), June 8, 2000;

Ref. 6 CN 1093370A (Jicai Medicine Research Inst B), October 12, 1994;

Ref. 7 Chemical Abstract No. 29525, Vol. 124, No. 3, January 15, 1996;

Ref. 8 WO 9804574A (Abbott Lab), February 5, 1998; and

Ref. 9 WO 0014099A (Kim Wan Joo), March 16, 2000.

All of the nine references, including their English translation where the references were published in foreign languages, were cited/submitted to the U.S. Patent Office in the Supplemental Information Disclosure Statement mailed on December 23, 2003. Therefore, the requirement of M.P.E.P. § 708.02 (VIII)(D) was satisfied, as all these references were already cited/submitted to the United States Patent and Trademark Office.

REQUIREMENT OF M.P.E.P. § 708.02 (VIII)(D) – DETAILED DISCUSSIONS

The references cited in the PCT search report were discussed in the enclosed PCT written opinion, a copy of which is enclosed herein. Applicants note that most of the references are related to azithromycin forms other than Form F. In addition, new claims 126-145 are directed to pharmaceutical compositions comprising substantially pure Form F and a pharmaceutically acceptable carrier or diluents. Therefore, Applicants have satisfied the requirement of M.P.E.P. § 708.02 (VIII)(D).

CONCLUSION

Applicants respectfully submit that the present petition has satisfied all the requirements of M.P.E.P. § 708.02 (VIII)(A), (B), (C), (D) and (E). Accordingly favorable consideration of the present petition is respectfully requested.

It is believed that no fee, other than the $130 fee set forth in 37 C.F.R. 1.17(h) is deemed necessary in connection with the filing of the present petition. However, if any other fees are required, the Commissioner is hereby authorized to charge any such fees to our Deposit Account No. 16-1445.

Date: 04/29/05

Respectfully submitted,

lance liu

Lance Y. Liu
Attorney for Applicant(s)
Reg. No. 45,379

Customer No. 28523
Pfizer Inc.
Patent Department, MS 8260-1611
Eastern Point Road
Groton, Connecticut 06340
(860) 686-1652

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 02/01570

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 C07H17/08

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 C07H

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 298 650 A (PFIZER) 11 January 1989 (1989-01-11) cited in the application page 4 method B	1,2,15
P,A	EP 1 103 558 A (ASTUR PHARMA S A) 30 May 2001 (2001-05-30) page 4; table	1,2,15
A	WO 01 00640 A (LUDESCHER JOHANNES ;GARCIA RAFAEL (ES); BIOCHEMIE SA (ES); DIAGO J) 4 January 2001 (2001-01-04) page 10, line 26 - line 28	1,4,5, 8-13
X	CA 2 245 398 A (MOTAMEDI M., KARIMIAN K., APOTEX INC.) 21 February 2000 (2000-02-21) whole document	1,4,5, 8-13

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
1 October 2002	11. 1. 10. 02

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Klein, D

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 02/01570

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00 32203 A (SINGER CLAUDE ;TEVA PHARMA (IL); ARONHEIM JUDITH (IL); TEVA PHARMA) 8 June 2000 (2000-06-08) cited in the application whole document	1,4,5, 8-13
A	CN 1 093 370 A (JICAI MEDICINE RESEARCH INST B) 12 October 1994 (1994-10-12)	
X	& CHEMICAL ABSTRACTS, vol. 124, no. 3, 15 January 1996 (1996-01-15) Columbus, Ohio, US; abstract no. 29525, abstract	1-15
X	WO 98 04574 A (ABBOTT LAB) 5 February 1998 (1998-02-05) examples	1-15
A	WO 00 14099 A (KIM WAN JOO ;LEE KYOUNG IK (KR); LEE TAE SUK (KR); LEE GWAN SUN (K) 16 March 2000 (2000-03-16) the whole document	

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB 02/01570

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1(part), 2, 15

   Crystals of azithromycin obtained in non polar solvents :
   monohydrate monocyclohexane solvate of azithromycin (form D).
   monomonomethyl tertiobutyl ether solvate of azithromycin (form R).

2. Claims: 1(part), 3, 14

   Crystals of azithromycin obtained in the presence of THF :
   monohydrate monotetrahydrofuran solvate of azithromycin (form E).
   monohydrate hemitetrahydrofuran solvate of azithromycin (form Q).

3. Claims: 1(part), 4, 5, 8-13

   Crystals of azithromycin consisting in alcohol solvates:

   Forms F, H, J, M, N, O, P.

4. Claims: 6, 7

   Crystals of azithromycin obtained in the sesquihydrate form:
   (form G).

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IB 02/01570

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
EP 0298650	A	11-01-1989	WO	8900576 A1	26-01-1989
			AP	44 A	27-07-1989
			AT	72446 T	15-02-1992
			AU	604553 B2	20-12-1990
			AU	1883988 A	12-01-1989
			BA	98213 B1	02-08-1999
			BG	47348 A3	15-06-1990
			CA	1314876 A1	23-03-1993
			CN	1030422 A ,B	18-01-1989
			CS	8804896 A2	14-03-1990
			CY	1776 A	20-10-1995
			DD	271705 A5	13-09-1989
			DE	3868296 D1	19-03-1992
			DK	380688 A	10-01-1989
			EP	0298650 A2	11-01-1989
			ES	2038756 T3	01-08-1993
			FI	900087 A ,B,	08-01-1990
			GR	3003737 T3	16-03-1993
			HK	127594 A	25-11-1994
			HU	9500738 A3	28-11-1995
			IE	60354 B	29-06-1994
			IL	86979 A	15-11-1992
			IN	168879 A1	29-06-1991
			JP	1038096 A	08-02-1989
			JP	1903527 C	08-02-1995
			JP	6031300 B	27-04-1994
			KR	9006218 B1	25-08-1990
			LV	10624 A	20-04-1995
			MX	12213 A	01-05-1993
			NZ	225338 A	26-02-1990
			OA	8743 A	31-03-1989
			PT	87933 A ,B	30-06-1989
			RO	107257 B1	30-10-1993
			SG	27794 G	14-10-1994
			SI	8811325 A8	31-12-1996
			RU	2066324 C1	10-09-1996
			US	6268489 B1	31-07-2001
			YU	132588 A1	28-02-1990
			ZA	8804925 A	28-02-1990
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			EP	1234833 A2	28-08-2002
			JP	2001187797 A	10-07-2001
			PL	344101 A1	04-06-2001
			TR	200003474 A2	23-07-2001
			US	6451990 B1	17-09-2002
WO 0100640	A	04-01-2001	AU	5820400 A	31-01-2001
			WO	0100640 A1	04-01-2001
			EP	1189915 A1	27-03-2002
CA 2245398	A		NONE		
WO 0032203	A	08-06-2000	AU	3106500 A	19-06-2000
			BG	105547 A	31-12-2001
			CN	1334735 T	06-02-2002
			CZ	20011886 A3	17-10-2001
			EP	1152765 A1	14-11-2001

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IB 02/01570

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 0032203 A		LV 12735 A	20-10-2001
		LV 12735 B	20-03-2002
		PL 347971 A1	06-05-2002
		SI 20639 A	28-02-2002
		WO 0032203 A1	08-06-2000
		US 2002007049 A1	17-01-2002
CN 1093370 A	12-10-1994	CN 1114960 A ,B	17-01-1996
WO 9804574 A	05-02-1998	US 5844105 A	01-12-1998
		AU 733646 B2	17-05-2001
		AU 3740597 A	20-02-1998
		EP 0915899 A1	19-05-1999
		JP 2002514171 T	14-05-2002
		WO 9804574 A1	05-02-1998
WO 0014099 A	16-03-2000	EP 1112280 A1	04-07-2001
		JP 2002524465 T	06-08-2002
		WO 0014099 A1	16-03-2000

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:
LUMB, Trevor J.
PFIZER Inc
201 Tabor Road, Morris Plains,
New Jersey 07950
ETATS-UNIS D'AMERIQUE

MAR 10

WRITTEN OPINION

(PCT Rule 66)

	Date of mailing *(day/month/year)* 04/03/2003
Applicant's or agent's file reference PC11724ABCZ	**REPLY DUE** within 1 / 00 months/days from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IB 02/01570	01/05/2002	22/05/2001

International Patent Classification (IPC) or both national classification and IPC
C07H17/08

Applicant
PFIZER PRODUCTS INC.et al.

1. This written opinion is the first drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I [X] Basis of the opinion
- II [ ] Priority
- III [X] Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV [X] Lack of unity of invention
- V [X] Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI [ ] Certain documents cited
- VII [ ] Certain defects in the international application
- VIII [ ] Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4*bis*. For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 22/09/2003

Name and mailing address of the IPEA/
European Patent Office
D-80298 Munich
Tel. (+49-89) 2399-0, Tx: 523656 epmu d
Fax: (+49-89) 2399-4465

Authorized officer
Examiner

Formalities officer
(incl. extension of time limits)
Tel. (+49-89) 2399 2828

I. Basis of the opinion

The basis of this written opinion is the application as originally filed.

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

If all the additional search fees, which the applicant has been invited to pay, have not been paid, then all the inventions or groups of inventions corresponding to the unpaid fees will not have been searched. This means that the question of whether the claimed invention appears to be novel, to involve an inventive step, or to be industrially applicable has not been and will not be the subject of the international preliminary examination in respect of the claims corresponding to these inventions or groups of inventions (Article 17(3)(a) and Rule 66.1(e) PCT; see also international search report).

IV. Lack of unity of invention

The objection as to lack of unity raised in the international search report is maintained. The reasons for the objection are the same as those indicated in the international search report.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability

1. To the extent that the international preliminary examination has been carried out (see item III above), the following is pointed out:

2. In light of the documents cited in the international search report, it is considered that the invention as defined in at least some of the claims, which have been the subject of an international search report, does not appear to meet the criteria mentioned in Article 33(1) PCT, i.e. does not appear to be novel and/or to involve an inventive step (see international search report, in particular the documents cited X and/or Y and corresponding claim references).

3. If amendments are filed, the applicant should comply with the requirements of Rule 66.8 PCT and indicate the basis of the amendments in the documents of the application as originally filed (Article 34 (2) (b) PCT) otherwise these amendments may not be taken into consideration for the establishment of the international preliminary examination report. The attention of the applicant is drawn to the fact that if the application contains an unnecessary plurality of independent claims, no examination of any of the claims will be carried out.

NB: Should the applicant decide to request detailed substantive examination, then an international preliminary examination report will normally be established directly. Exceptionally the examiner may draw up a second written opinion, should this be explicitly requested.

AMENDMENTS TO THE CLAIMS

1 - 125. (Canceled).

126. (NEW) A pharmaceutical composition comprising substantially pure Form F and a pharmaceutically acceptable carrier or diluents.

127. (NEW) The pharmaceutical composition of claim 126, wherein said substantially pure Form F is characterized as containing 2-5% water and 1-5% ethanol by weight in a powder sample.

128. (NEW) The pharmaceutical composition of claim 127, wherein said substantially pure Form F is characterized as having a ^{13}C solid state NMR spectrum comprising at least one peak with chemical shift of about 179.5 ppm.

129. (NEW) The pharmaceutical composition of claim 128, wherein said substantially pure Form F is characterized as having a ^{13}C solid state NMR spectrum further comprising a peak with chemical shifts of about 178.6 ppm.

130. (NEW) The pharmaceutical composition of claim 129, wherein said substantially pure Form F is characterized as having a ^{13}C solid state NMR spectrum further comprising a peak with chemical shifts of about 58.0 ppm.

131. (NEW) The pharmaceutical composition of claim 130, wherein said substantially pure Form F is characterized as having a ^{13}C solid state NMR spectrum further comprising a peak with chemical shifts of about 17.2 ppm.

132. (NEW) The pharmaceutical composition of claim 131, wherein said substantially pure Form F is characterized as having a ^{13}C solid state NMR spectrum further comprising a peak with chemical shifts of about 10.1 ppm.

133. (NEW) The pharmaceutical composition of claim 132, wherein said substantially pure Form F is characterized as having a ^{13}C solid state NMR spectrum further comprising a peak with chemical shifts of about 9.8 ppm.

134. (NEW) The pharmaceutical composition of claim 133, wherein said substantially pure Form F is characterized as having a ^{13}C solid state NMR spectrum further comprising a peak with chemical shifts of about 9.3 ppm.

135. (NEW) The pharmaceutical composition of claim 134, wherein said substantially pure Form F is characterized as having a ^{13}C solid state NMR spectrum further comprising a peak with chemical shifts of about 7.9 ppm.

136. (NEW) The pharmaceutical composition of claim 135, wherein said substantially pure Form F is characterized as having a ^{13}C solid state NMR spectrum further comprising a peak with chemical shifts of about 6.6 ppm.

137. (NEW) The pharmaceutical composition of claim 126, wherein said substantially pure Form F comprises 82% or more by weight of form F azithromycin.

138. (NEW) The pharmaceutical composition of claim 126, wherein said substantially pure Form F comprises 84% or more by weight of form F azithromycin.

139. (NEW) The pharmaceutical composition of claim 126, wherein said substantially pure Form F comprises 86% or more by weight of form F azithromycin.

140. (NEW) The pharmaceutical composition of claim 126, wherein said substantially pure Form F comprises 88% or more by weight of form F azithromycin.

141. (NEW) The pharmaceutical composition of claim 126, wherein said substantially pure Form F comprises 90% or more by weight of form F azithromycin.

142. (NEW) The pharmaceutical composition of claim 126, wherein said substantially pure Form F comprises 94% or more by weight of form F azithromycin.

143. (NEW) The pharmaceutical composition of claim 126, wherein said substantially pure Form F comprises 96% or more by weight of form F azithromycin.

144. (NEW) The pharmaceutical composition of claim 126, wherein said substantially pure Form F comprises 98% or more by weight of form F azithromycin.

145. (NEW) The pharmaceutical composition of claim 126, wherein said substantially pure Form F comprises 99% or more by weight of form F azithromycin.

CLAIMS

What is claimed is:

1. A crystalline form of azithromycin selected from the group consisting of forms D, E, substantially pure F, substantially pure G, H, J, M substantially in the absence of azithromycin dihydrate, N, O, P, Q, and R.

2. A crystalline form of azithromycin according to claim 1 wherein said form is form D and is further characterized as having a 13C solid state NMR spectrum having a peaks with chemical shifts of about 178.1 ppm, 103.9 ppm, 95.1 ppm, 84.2 ppm, 10.6 ppm, 9.0 ppm and 8.6 ppm.

3. A crystalline form of azithromycin according to claim 1 wherein said form is form E.

4. A crystalline form of azithromycin according to claim 1 wherein said form is substantially pure form F and is further characterized as having a 13C solid state NMR spectrum having a peaks with chemical shifts of about 179.5 ppm, 178.6 ppm, 58.0 ppm, 10.1 ppm 9.8 ppm, 9.3 ppm, 7.9 ppm and 6.6 ppm.

5. A crystalline form of azithromycin according to claim 4 wherein said azithromycin comprises 90% or more by weight of form F azithromycin.

6. A crystal form according to claim 1 wherein said form is substantially pure form G and is further characterized as having a 13C solid state NMR spectrum having a peaks with chemical shifts of about 179.5 ppm, 10.4 ppm, 9.9 ppm, 9.3 ppm, 7.6 ppm and 6.5 ppm.

7. A crystalline form of azithromycin according to claim 6 wherein said azithromycin comprises 90% or more by weight of form G azithromycin.

8. A crystal form according to claim 1 wherein said form is form H and is further characterized as having a 13C solid state NMR spectrum having a peaks with chemical shifts of about 179.5 ppm, 178.7 ppm, 9.9 ppm, 9.1 ppm, 7.9 ppm and 7.0 ppm.

9. A crystal form according to claim 1 wherein said form is form J and is further characterized as having a 13C solid state NMR spectrum having a peaks with chemical shifts of about 179.6 ppm, 178.4 ppm, 25.2 ppm, 11.5 ppm, 10.0 ppm, 9.3 ppm, 8.1 ppm and 6.8 ppm.

10. A crystal form according to claim 1 wherein said form is form M substantially in the absence of azithromycin dihydrate and is further characterized as having a 13C solid state NMR spectrum having a peaks with chemical shifts of about 179.6 ppm, 41.9 ppm, 26.0 ppm, 16.3 ppm, 10.3 ppm, 9.6 ppm, 9.3 ppm, 7.7 ppm and 7.1 ppm.

11. A crystal form according to claim 1 wherein said form is form N and is further characterized as having a 13C solid state NMR spectrum having a peaks with chemical shifts of about 179.6 ppm, 178.7 ppm, 105.6 ppm, 58.1 ppm, 26.0 ppm, 9.9 ppm, 9.4 ppm, 7.9 ppm, and 6.6 ppm.

12. A crystal form according to claim 1 wherein said form is form O.

13. A crystal form according to claim 1 wherein said form is form P.

14. A crystal form according to claim 1 wherein said form is form Q.

15. A crystal form according to claim 1 wherein said form is form R and is further characterized as having a 13C solid state NMR spectrum having a peaks with chemical shifts of about 177.9 ppm, 103.6 ppm, 95.3 ppm, 10.3 ppm, 9.6 ppm, 8.9 ppm, and 8.6 ppm.